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| BROOKHAVEN NATIONAL LABORATORY GENERAL CLINICAL RESEARCH CENTER POLICY | GCRC POLICY: IC-13 | PAGE 1 OF 1 |
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| SUBJECT: Animal Studies at Clinical Facilities | EFFECTIVE DATE: 11/16/06 | |
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1.0 PURPOSE AND SCOPE

This document defines the procedures that must be followed when facilities which are primarily used for human research are also used for animal studies, (see Attachment 1 for listing). The requirements apply to all research personnel.

2.0 APPLICABLE DOCUMENTS/DEFINITIONS

N/A

3.0 GENERAL NOTES

The first priority for the use of Medical Department General Clinical Research Center (GCRC) and GCRC Satellite facilities is for treatment or clinical study of research subjects. However, these facilities may be used by BNL researchers for animal studies, dosimetry and other physics experiments, etc. In those studies, the researchers are guests of the facilities, and after use they are responsible for returning the facilities to their usual state of cleanliness and availability for the next subjects. If this is not done by the researchers to the satisfaction of the facility operators, the privilege to use the facilities may be revoked by the cognizant facility manager. Special care must be taken by the researcher when studies with animals are involved. It is imperative that cross-infection between animals and people is prevented, especially as zoonotic transmission to humans and allergic reactions of some subjects to animal hair and dander are possible.

4.0 MATERIALS

Cleaning supplies and checklist

5.0 POLICIES AND PROCEDURES

The following procedure shall be followed by the researcher:

1. Prior to beginning such work, an experimental review must be conducted by the ESH Committee.
2. For animal studies the researcher shall obtain prior approval from the BNL Institutional Animal Care and Use Committee (IACUC).
3. The researcher and his/her collaborators shall have completed all required training prior to the study.
4. The researcher shall follow the Infection Control Protocol (Attachment 2) when animals are involved.
5. A schedule of proposed animal studies shall be submitted to, and must be approved by, the Facility Supervisor/Manager or designee, at least 7 days before the study and shall be kept by the Infection Control Practitioner.
6. An Infection Control Checklist (Attachment 3) documenting the required procedures, shall be used by the researcher in preparing for, and conducting, the study, and in the subsequent cleanup.
 - a. A copy of the completed checklist shall remain at the facility to be used by the operator to determine that the facility is ready for subject use.
 - b. If the operator determines that the facility is not left by the researcher in the appropriate condition for subject use, the operator shall immediately notify the Infection Control Practitioner.
 - c. The Infection Control Practitioner shall immediately contact the researcher to clean up the facility and, if necessary, coordinate the appropriate cleanup with the custodians and other personnel.
7. Additional requirements imposed by Facility Supervisors may be included as additional attachments.

6.0 RECORDS

The checklist to be maintained by the Principal Investigator/Facility Supervisors in each facility and the Infection Control Practitioner.

7.0 ATTACHMENTS

1. Facilities used for both human and animal research
2. Infection Control Protocol for Animal Studies at Subject Treatment or Diagnostic Facilities
3. Infection Control Checklist for Animal Studies at Subject Treatment or Diagnostic Facilities

The only official copy of this file is the one online at the Medical Department website under "Clinical Research Center Policy Manual." Before using a printed copy, verify that it is the most current version by checking the document effective date on the website.

List of facilities in which both human and animal research is conducted:
6/06

PET
MRI

INFECTION CONTROL PROTOCOL FOR ANIMAL STUDIES AT SUBJECT TREATMENT OR DIAGNOSTIC FACILITIES

The Medical Department is primarily devoted to research and therefore animal studies will be periodically conducted in facilities used for treating or studying subject/participants. Strict infection control guidelines shall therefore be used:

1. Only animal studies directly relevant to the IACUC research protocol requested, reviewed and approved shall be allowed.
2. The studies shall be performed only in the facility identified in the IACUC protocol. All studies shall have the written approval of the facility supervisor or designee of the facility involved.
3. Whenever possible, animal studies should be conducted after subject/participants' treatments or studies are completed. The researcher shall contact the person coordinating the work at each facility to schedule the non-subject/participant work.
4. The studies shall be initiated and completed within an agreed upon time frame as identified in the protocol.
5. A predetermined, precise route of transport of the animals from the Animal Facility to the site of experimentation and return shall be followed for each experiment.
6. As required, the animal(s) shall be prepared (i.e., anesthetized, where applicable, shaved, etc.) in the Animal Facility or researcher's laboratory and shall remain totally anesthetized during the transfer to the Subject Facility's experimentation site. Any initial surgery should be accomplished, whenever possible, before transfer to the experimentation site. The animals shall remain anesthetized during the course of the experimentation. If the experiment is to take place at a satellite facility, a BNL van shall be used to transfer the animals. Protective equipment shall be used in the van while animal is present. After the animal is removed the van needs to be disinfected. A decontamination kit is also provided in the van.
7. Large animals shall be covered with a sheet or disposable paper during transportation to and from the Subject Facility. Smaller animals shall be transported in clean cages with clean bedding. These cages shall then be covered with a sheet so that the animal(s) shall not be visible to the public during the transport.
8. Precautions shall be taken during the transport and experiment to prevent the loss of feces, urine, blood and secretions into the environment. Large animals shall be diapered to prevent loss of urine. In addition all procedures shall be carefully performed to minimize the creation of aerosols. Therefore, certified safety cabinets or other appropriate combinations of personal protection or physical containment devices, such as special protective clothing, respirators, centrifuge safety cups and sealed centrifuge rotors shall be used. The risk of infected aerosols from animals or their bedding can be reduced if animals are housed in partial containment caging, i.e., solid wall and bottom cages covered by filter bonnets. Larger animals especially primates need to be transported in covered/filtered transport cages.
9. All equipment and facility surfaces which may come in contact with animals shall be completely covered with impermeable drapes during the studies.
10. All instruments and equipment that come into direct contact with the animal shall either be disposable or obtained from the Animal Facility. No equipment shall be utilized in the experiment(s) that will come directly in contact with a participant.
11. Researchers and assistants shall follow all appropriate facility procedure requirements.
12. Facility doors shall be left closed when any experiments are in progress.
13. The researcher and assistants shall wear clean laboratory coats for the study. Laboratory clothing worn in the Animal Facility shall not be worn in the subject area.
14. After the studies are finished, it is the researcher's responsibility to leave the Facility in a clean condition and ready to receive subjects. All non-sharp disposables shall be placed in a leak-tight plastic bag or plastic lined ice cream container (ICC). This shall include all drapes, waste, disposable equipment, and other materials and drugs used during the course of the experimentation. The researcher shall seal the bag or cover the ICC and remove it from the Facility. The researcher shall place all sharps in a sharps container brought along for this purpose, and shall remove it from the Facility at the end of the study.
15. The researcher shall wipe all surfaces used in the study with a freshly prepared disinfectant (Cidex, Metrex, Maxima or equivalent).

- a. Work surfaces shall be cleaned from cleanest to dirtiest areas.
 - i. Clean from top to bottom.
 - ii. Remove loose dirt/debris before washing.
- b. Damp dusting/washing shall be performed to avoid cleaning methods that generate dust aerosols.
- c. Cleaning supplies or equipment shall not be stored in subject rooms.

16. The researcher shall bring his own supplies for the study. However, disinfectant and disposable cleaning clothes may be available in the Subject Facility.

17. Personnel shall wash their hands after handling the animals, before entering the Facility, and before leaving the Facility.

18. Infection Control surveillance shall be done periodically by the Infection Control Practitioner and facility liaison operator to check for cleanliness after the study and before the next subject/participant is treated or studied. The Infection Control Practitioner shall use a review form that provides a record of the work practices and compliance with this procedure.

- a. If the operator determines that the facility is not left by the researcher in the appropriate condition for subject use, he/she shall immediately notify the Infection Control Practitioner.
- b. The Infection Control Practitioner shall immediately contact the researcher to clean up the facility and, if necessary, coordinate the appropriate cleanup with the custodians and other personnel.

IN ADDITION THE FOLLOWING RULES AND REGULATIONS PERTAIN TO HANDLING THE MACAQUE MONKEYS:

The routine screening of macaques for evidence of B virus infection is not recommended. All macaque monkey not known to be free of B virus should be regarded as infected because viral shedding is intermittent and can occur in the absence of visible lesions, B-virus or positive titer. Capturing, restraining, or otherwise handling fully awake macaques with bare hands is not allowed. Macaque handlers should remove physically active animals from cages only with arm-length reinforced leather gloves. In addition, handlers must be additionally protected with a long-sleeved garment to prevent scratches and a face shield and goggles to prevent exposure of eyes and mucous membranes to macaque secretions. Latex or vinyl gloves must be worn when the animal is chemically restrained. Booties shall also be worn while in the animal rooms.

Cages and other equipment that may be contaminated with virus must be free of sharp edges and corners that may cause scratches or wounds. In addition, they should be arranged in animal housing areas so that the risk of workers being accidentally grabbed or scratched is minimized. Animals should preferably be housed only 1 per cage to reduce risk of animal escape and injury to personnel..

Persons who handle macaques, including, primate veterinarians and scientific investigators, shall be trained in proper methods of restraint and in the use of protective clothing to help prevent bites and scratches. They shall also be educated concerning the nature of B virus infection and the need to prevent bites, scratches, and other exposure to macaque secretions. A wound or injury should be cleansed immediately by thoroughly scrubbing and cleansing with soap and water or a topical antimicrobial agent (povidine iodine or chlorhexidine) for 15 minutes. OMC has distributed Macaque bite wound kits containing materials needed for cleansing these wounds. Follow OMC's Procedures For The Management of Macaque Exposures. After flushing the wound you should then go immediately to OMC who reports it to your supervisor and ESH. The incident is also reported to the animal care supervisor and recorded in a bite/scratch log. Neither hyperimmune human B virus globulin nor vaccine against B virus is currently available. Persons who are either immunosuppressed because of medication or underlying medical conditions may be at higher risk for B virus infection. Call 2222 (or 911) for serious injuries or if assistance is needed in cleansing the wound.

For further information see CDC's "Guidelines for Prevention of Herpesvirus Simiae (B virus) Infection in Monkey Handlers **MMWR** Oct 23, 1987/36(41):680-682,687-689

INFECTION CONTROL CHECKLIST FOR ANIMAL STUDIES
AT SUBJECT TREATMENT OR DIAGNOSTIC FACILITIES
6/05

DATE: _____ RESEARCHER: _____ IACUC PROTOCOL NO.
ANIMAL SPECIES: _____

1. _ Bring the following items with you to the Subject Facility:

- A. Plastic lined ice cream containers and plastic bags
- B. Sharps containers
- C. Change of lab coats
- D. Diapers
- E. Disinfectant

2. _ Make sure animals are totally contained, shaved, anesthetized (where applicable) and covered before transporting them to the Patient Facility.

3. _ Wash your hands after working with the animals in the Animal Facility before entering the Patient Facility.

4. _ Change your lab coat before entering Subject Facility.

5. _ Make sure the door to the Facility is closed and no food or drink is brought into the Facility.

6. _ Cover all surfaces in the Subject Facility in contact with the animal.

7. _ When leaving the Facility, disinfect all surfaces thoroughly and take everything with you.

8. _ Before leaving the Facility, make sure you wash your hands.

9. _ If you are using the van, lay diapers down before placing animal in the van. Labcoat , gloves and mask are used if you are transporting Macaques. A sheet is hung in the van to separate the animals from the driver. Make sure you disinfect the van after use.

The above procedures have been followed by the researcher and assistants.

Researcher:

Assistants:
